

REMARKS/ARGUMENTS

Applicant would like to thank the Examiner for the careful consideration given the present application. The application has been carefully reviewed in light of the Office action, and amended as deemed necessary by applicant to place the application into condition for allowance.

Specifically, by this Amendment, claims 1-4, 6, 7, 9, 11, 12, 18, 20, 23, 32-36, 39, 44, 46-49, 53-55 and 57-59 have been amended. No claims have been canceled and no new claims have been added to the application. Accordingly, claims 1-40 and 44-59 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner rejected claims 3-40 and 44-59 under 35 U.S.C. §112, second paragraph, as failing to set forth the subject matter which applicant regards as the invention. Specifically, the Examiner contends that claim 3 is indefinite because it includes a clause beginning with the word "preferably". In this Amendment, claim 3 has been amended to delete the clause beginning with the word "preferably". Similar amendments have also been made to claims 6, 12, 18, 20, 32-36, 39, 44, 46-48, 53 and 54.

Also in the prior Office Action, the Examiner rejected claim 9 under 35 U.S.C. §112, second paragraph, on grounds that the phrase "an amount of" seemed indefinite. Although applicant disagrees with the Examiner on this point, claim 9 has been amended to delete this language. A similar amendment has also been made to claim 7.

In the prior Office Action, the Examiner requested correction of the Markush language in claim 23. In this Amendment, claim 32 has been amended to use the

phrase "selected from the group consisting of". Similar amendments have been made to claims 4, 39 and 48.

In the prior Office Action, the Examiner requested that the compositions previously referenced by the abbreviations "CSH" and "CSD" be written out in long form and that the abbreviations "CSH" and "CSD" be deleted from claim 46. Claim 46 has been so amended. In addition, the Examiner requested that the words "such as" be deleted from claim 47. Claim 47 has been so amended. The Examiner objected to claim 55 on grounds that it impermissibly set forth a "use" claim rather than a method claim. By this amendment, claim 55 has been rewritten in proper method form as suggested by the Examiner. And, the Examiner requested that the word "A" be added as the first word of claim 57, that the word "The" be added as the first word of claim 58 and that the word "A" be added as the first word of claim 59. By this amendment, the requested changes to claims 57-59 have been made. In view of the amendments made to the claims, reconsideration of the claim rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

Also in the prior Office Action, the Examiner rejected claims 1-40 and 44-59 under 35 U.S.C. §103(a) as being unpatentable over Tofighi et al. (US 2003/0120351 A1)¹, Khairoun et al. (US 7,351,280 B2), Lee et al. (US 7,150,879 B1 or US 6,953,594 B2), or Chow et al. (US 7,294,187 B2). The Examiner contends that all of the cited references teach a composition comprising amorphous calcium phosphate ("ACP") and the other claimed components in amounts overlapping applicant's instant invention. The Examiner further contends that the addition of further additives, the control of particle sizes and the use of setting retarders or accelerators

¹ The Examiner references Tofighi et al. as Rey Christian et al. in the Office Action.

is conventional. The Examiner references the PCT International Search Report, which cites various paragraphs of Tofighi et al. The Examiner contends that Khairoun et al. teaches an ACP cement that comprises phases of ACP as well as alpha tri-calcium phosphate (α -TCP) and tetra-calcium phosphate (TTCP) in amounts that overlap applicant's claims. The Examiner contends that Lee et al. '879 teaches ACP and α -TCP together as a calcium phosphate cement composition that includes overlapping ranges of amounts, and that Lee et al. '594 teaches a calcium phosphate cement comprising amorphous calcium phosphate. Finally, the Examiner contends that Chow et al. teaches a calcium phosphate cement comprising a combination or mixture of α -TCP, β -TCP and ACP in amounts that overlap applicants claims.

In response, applicant notes that claim 1 of the present invention is drawn to a hydraulic cement comprising powder particles of an anhydrous, amorphous calcium phosphate (ACP), which is obtained by milling a calcium phosphate synthesized above 500°C. The ACP used in the calcium phosphate cements according to Khairoun et al. (US 7,351,280 B2), Lee et al. (US 7,150,879 B1 and US 6,953,594 B2) and Chow et al. (US 7,294,187 B2) is obtained by precipitation (i.e., a wet method) rather than by a process in which the ACP is synthesized above 500°C (i.e., by calcination/sintering) as claimed in the present application.

Crystallographically, both phases look amorphous in x-ray diffraction (no diffraction peaks), but chemically, ACP obtained by precipitation contains bound water whereas ACP obtained by calcination/sintering is basically free of bound water. This can be demonstratively proven by heating the two types of ACP powder to a temperature of about 800-900°C. The "precipitated" ACP would present a weight loss resulting from

the release of water whereas the ACP powder obtained by milling calcium phosphate synthesized above 500°C would maintain essentially the same weight (thus indicating no water loss). The ACP powders used in Khairoun et al., Lee et al. ('879 and '594) and Chow et al. are chemically different than the ACP powders claimed in the present application, and produce different, less advantageous, results when used in a calcium phosphate cement for surgical use.

Only Tofighi et al. teaches an ACP obtained by milling a calcium phosphate synthesized above 500°C. To distinguish Tofighi et al., applicant has added the limitations of claims 7 and 9 to claim 1, which now specifies that the first component (powder particles) further comprises calcium sulfate dihydrate or calcium sulfate hemihydrate. Applicant notes that Tofighi et al. does not teach the use of calcium sulfate dihydrate or calcium sulfate hemihydrate in the first component (powder particles) of a calcium phosphate cement. And, applicant asserts that it would not have been obvious to one having ordinary skill in the art at the time of applicant's invention to add one or both of such calcium phosphate materials to the first component (powder particles) of a calcium phosphate cement according to Tofighi et al.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. LUS-16732.

Respectfully submitted,

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